DEC 12 2002

510(k) SUMMARY
Baxter AURORA™ System 1000® Series
Single Patient Dialysis Delivery System

Submitter's name, addresss, phone, fax, contact person	Baxter Healthcare Corporation Renal Division 1620 Waukegan Road McGaw Park, IL 60085 Phone: (847) 473-6335 Fax: (847) 473-6952 Contact: Robert L. Wilkinson, RAC
Date prepared	December 12, 2002
Trade name of device	Baxter AURORA™ System 1000® Series Single Patient Dialysis Delivery System
Common name	Hemodialysis System
Classification name	§ 21CFR 876.5860 High Permeability Hemodialysis System
Substantially equivalent devices	The predicate substantially equivalent devices include: System 1000® Series Dialysis Delivery Systems [510(k) numbers K910215 System 1000, Dialysis Delivery System, K954987 AltraTouch 1000 Machine, K955384 SND option, K964922 AutoStart option and K970446 Hematocrit and Blood Volume Monitor option and K992894 Meridian Hemodialysis Machine].
Description of the device	The AURORA™ System 1000 Series Single Patient Dialysis Delivery System is a dialysate proportioning system for hemodialysis. The system fulfills the following functions: 1. Mixes concentrate with water in the appropriate proportions to produce dialysate. 2. Delivers dialysate at the appropriate temperature and ionic concentration to the dialyzer. 3. Removes the appropriate amount of liquid from the patient's blood. 4. Along with the dialyzer and blood pump acts as a total artificial kidney.

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Baxter AURORA™ System 1000® Series
Single Patient Dialysis Delivery System
Continued

Intended use of the device	The AURORA™ System Series 1000® Single Patient Dialysis Delivery System is part of a high permeability hemodialysis system which consists of a controlled dialysate delivery system that incorporates an ultrafiltration controller to prevent excessive loss of water from the patient's blood, an extracorporeal blood set, and a high permeability dialyzer. The standard features of the AURORA™ System 1000® Series Single Patient Dialysis Delivery System includes a high blood flow rate capacity, automatic ultrafiltration control, standard and variable bicarbonate and sodium capabilities and automated chemical disingection. The AURORA™ System 1000® Series Single Patient Dialysis Delivery System will operate in either the bicarbonate or acetate mode for concentrates. The AURORA™ System 1000® Series Single Patient Dialysis Delivery System is designed to operate in the chronic and acute dialysis environment. It is not for home use.
Comparison of technological characteristics between new and predicate device	The AURORA™ System 1000® Series Single Patient Dialysis Delivery System is built with the same fluid path and hardware components as the predicate System 1000® Delivery Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2002

Robert L. Wilkinson, RAC
Director of Regulatory Affairs
Baxter Healthcare Corporation
1620 Waukegan Road
MCGAW PARK IL 60085

Re: K013562
Trade/Device Name: AURORA™ System 1000® Series Single Patient Delivery System
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: September 12, 2002
Received: September 13, 2002

Dear Mr. Wilkinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(K) Number (if known): K013562

Device Name:

Baxter AURORA™ System 1000® Series Single Patient Dialysis Delivery System

Model: SYS 1000, L3 with N100 Arm, 4B Software

Indications for Use:

The AURORA™ System 1000® Series Single Patient Dialysis Delivery System is part of a high permeability hemodialysis system which consists of a controlled dialysate delivery system that incorporates an ultrafiltration controller to prevent excessive loss of water from the patient's blood, an extracorporeal blood set, and a high permeability dialyzer. The standard features of the Aurora System 1000 include a high blood flow rate capacity, automatic ultrafiltration control, standard and variable bicarbonate and sodium capabilities and automated chemical disinfection. The Aurora System 1000 Instrument will operate in either the bicarbonate or acetate mode for concentrates.

The AURORA™ System 1000® Series Single Patient Dialysis Delivery System is designed to operate in the chronic and acute dialysis environment. It is not for home use.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109

David A. Lepore
(Divisional Sign-Off)
Division of Reproductive, Abdominal, & Radiological Devices
510(k) Number K013562

(Optional Format 1/2/96)